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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,800	03/30/2005	David C Racenet	2863(203-3511)	5353

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EXAMINER

LOPEZ, MICHELLE

ART UNIT PAPER NUMBER

3721

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/529,800	Applicant(s) RACENET, DAVID C	
	Examiner Michelle Lopez	Art Unit 3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-54 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 26-54 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/19/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-25 have been canceled

New claims 26-54 have been added.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has complied with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] for the provisional application 60/416088 filed 10/04/2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following limitations in the claims lacks antecedent basis: in claim 26, line 5, "the proximal end"; in claim 38, "the maximum tissue gap"; in claim 39, "its advanced position"; in claim 46, "each of the at least one staple" and "the staple"; and in claim 48, "the longitudinal axis".

The scope of claim 37 is unclear in that the result of "rotation of the tool assembly" is merely a function and positive structure to perform that function, i.e. "that rotation of the center rod effects rotation of the dynamic clamping member", is not recited. If applicant intends to rely on the function, the structure performing it should be recited or it should be set forth in "means plus function" terms.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-27, 34, 38, 42-43, 45-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Milliman (6,669,073).

Milliman discloses a tool assembly comprising an anvil 20 and a cartridge assembly 18, the cartridge assembly having a plurality of fasteners and being movable in relation to the anvil between a spaced position and an approximated position, the cartridge assembly and the anvil defining a tissue gap in the approximated position; a clamp member 202 and a dynamic clamping member 278 (claim 26); a drive member 266 operably connected to the clamp member and the dynamic clamping member, the drive member being formed from a flexible cable and being movable to move the clamp member and the dynamic the dynamic clamping member between their first and second positions as shown on col. 13; 5-18, also see Figs. 45,49,52,57-61 (claim27); wherein the tool assembly is pivotally secured to a body portion 16 of a stapling device (claim 34); the dynamic clamping member includes a first flange portion positioned to engage a surface of the anvil and a second flange portion positioned to engage a surface of the cartridge assembly as shown in Fig. 49 (claim 38); a blade 280 formed on the dynamic clamping member (claims 42-43); wherein the first position of the dynamic clamping member is adjacent a proximal end of the tool assembly as shown in Fig. 49 and the second position of the dynamic

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clamping member is adjacent a distal end of the tool assembly as shown in Figs. 51-52 (claim 45); a sled and at least one pusher 228, the sled being driven by the dynamic clamping member as shown in Figs. 24-26 and 51-52 (claims 46 and 51); a plurality of staples and pushers as shown in Figs. 25-26 (claims 47 and 52); a lower flange portion having a rounded cross-section 287 as shown in Fig. 49 (claim 48); a knife blade 280 formed on a central body portion of the dynamic clamping member (claims 49-50); wherein the upper and lower flange are substantially vertically aligned, see Fig. 49 (claim 53); wherein the knife blade 280 is disposed between the upper and lower flanges (claim 54).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28-33, 35-37, 39-41, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milliman (6,669,073) in view of Bolanos (5,690,269).

Milliman discloses the invention substantially as claimed including a flexible drive member as a center rod cable 266 (see Figs 57 and 60-61), but does not disclose wherein the drive member includes a coaxial drive cable including an outer sheath and a center rod. Bolanos teaches the concept of a drive member having a coaxial drive cable with an outer sheath 200 and a center rod 70 for the purpose of articulating an endoscopic portion. It would have been obvious to one having ordinary skill in the art to have provided Milliman's drive member as taught by Bolanos to articulate the tool assembly.

Bolanos also teaches wherein the center rod 70 is movable and axially movable with respect to the outer sheath (claims 29-30).

With respect to claim 31, it is deemed that Bolanos' center rod 70 is rotatable in relation to the outer sheath as shown in Fig. 8.

With respect to claim 32, Bolanos also shows wherein the outer sheath 200 is operably connected to the clamp member as shown in Fig. 12.

With respect to claim 33, Milliman shows wherein a center rod via 266 is operably connected to the dynamic clamping member via 270.

With respect to claims 35-36, Milliman does not specifically disclose a collar member pivotally secured to the body portion wherein the tool assembly is rotatably mounted to the collar member. Bolanos shows a collar member at the vicinity of 16 pivotally secured to the body portion 14 wherein the tool assembly 20 is rotatably mounted to the collar member as shown in Fig. 1 to permit articulation of the tool assembly. It would have been obvious to one having ordinary skill in the art to have provided Milliman's tool assembly as taught by Bolanos to permit articulation of the tool assembly.

With respect to claim 37, Milliman teaches wherein the center rod 266 is operable connected to the dynamic clamping member such that rotation of 266 via 28 effects rotation of tool assembly.

With respect to claim 39, Milliman does not specifically disclose wherein the clamp member 202 is annular. However, Bolanos shows an annular clamp member at the vicinity of 20 (see Fig. 4) to pivotally support a tool assembly. It would have been obvious to one having

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ordinary skill in the art to have provided Milliman's clamp member as taught by Bolanos to pivotally support the tool assembly.

With respect to claim 40, Milliman also discloses wherein the center rod 266 is a flexible cable.

With respect to claim 41, Milliman as modified by Bolanos does not specifically disclose wherein the outer sheath is selected from the group consisting of steel mesh, plastic, nitinol and Kevlar. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a material as claimed, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

With respect to claim 44, Bolanos also shows a drive collar wherein the outer sheath 200 is fixedly attached to the drive collar via 136 as shown in Fig. 12 (claim 44).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mastri was cited to show related inventions. Also, applications 10/871,342 and 10/529,799 were considered.

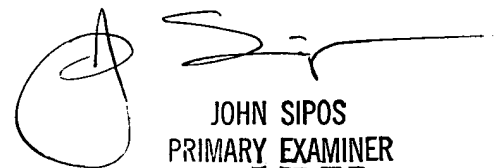
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Lopez whose telephone number is 571-272-4464. The examiner can normally be reached on Monday - Thursday: 8:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ML



JOHN SIPOS
PRIMARY EXAMINER